

REMARKS

Claims 28-39, 46 and 75 are in this application. Claim 28 has been amended and this will be discussed below.

According to the official action, Claims 28-35, 37-39, 46 and 75 are rejected under 35 USC §112 first paragraph as not being enabled. This is respectfully traversed.

Claim 28 has been amended and now reads as follows:

28. A method for improving physical work capacity of a human subject without a detectable change in plasma IGF-1 concentration said method comprising ingestion of a colostrum fraction prepared by a process comprising the steps of:

(a) subjecting colostrum to ultrafiltration to obtain an ultrafiltered colostrum retentate comprising colostrum derived growth factors and casein retained after ultrafiltration and

(b) subjecting the colostrum retentate to a spray drying process to obtain a colostrum fraction wherein after ingestion of the colostrum fraction one or more of endurance, ability to do more exercise, fatigue and recovery from exercise is improved.

Applicants consider that the Examiner's objection may relate to the general reference to colostrum derived growth factors and casein when in fact, the colostrum derived growth factors contained in the colostrum fraction are those retained after ultrafiltration. Support for this amendment is found on page 6, lines 5 and 6 of the specification.

The Examiner appears to have read Claim 28 incorrectly. The Examiner reads the claim as referring to the colostrum fraction without the presence of IGF-1. Correctly read,

the method disclosed in Claim 28 relates to improving physical work capacity without a detectable change in plasma IGF-1 concentration rather than without the presence of IGF-1.

Therefore, it is respectfully requested that this rejection be withdrawn.

According to page 3 of the Action, Claims 28-39, 46 and 75 are rejected under 35 USC 112, second paragraph. This is respectfully traversed.

In view of the amendment to Claim 28, it is respectfully requested that the rejection be withdrawn.

According page 4 of the Action, Claims 28-29, 46 and 75 are rejected as being anticipated under 35 USC 102(b) based on NZ282898. This is respectfully traversed.

Applicants assume that the reference to NZ282893 by the Examiner in the discussion of the rejection is incorrect and that the correct reference is NZ282893.

NZ282898 relates to preparing bovine insulin-like growth factor - 1 (IGF-1) from various sources including colostrum. The only example from which the bovine IGF-1 is obtained from colostrum is found in Example 7. However, in all of the Examples provided, the protein source (whey protein, cheese whey, non-sterilized skim milk, protein concentrates (WPC) and whey protein isolates (WPI)) were all run through a column such as SP-7XSEPHADEX, S-Spherosil, Indion S3, etc. so as to allow the bovine IGF-1 to adhere to the cation exchanger for subsequent elution with an appropriate eluting solution. The aim of this citation is to retrieve bovine IGF-1 from the protein source (e.g. colostrum) and then use that eluted bovine IGF-1 for improving physical work capacity.

The Examiner contends that the citation teaches preparing a colostrum fraction

which can improve exercise. The actual term "exercise" cannot be found in this citation and moreover, it does not refer to actual exercise but more to the bone reinforcement effect caused by the use of IGF-1 and its usefulness for preventing and treating osteoporosis.

The Examiner then cites various references to techniques used in fractionating the colostrum such as ultrafiltration (page 9, line 19) and the use of spray drying (page 9, line 25). However, none of the references to ultrafiltration or spray drying are used in combination with the fractionation of colostrum in the manner outlined in the present claims. For instance, the reference to ultrafiltration on page 9 is made to the eluate containing the bovine IGF-1 fraction and the use of the ultrafiltration is to desalt and concentrate the IGF-1 fraction. It is not used in respect of the colostrums *per se* but an eluate that is obtained after the colostrum has been run through the column. Moreover, once the colostrum is run through the column, the bovine IGF-1 fraction that has bound to the column would be eluted away from the main components of colostrum. The colostrum is not used with the eluted IGF-1.

In a similar manner, the Examiner refers to parameters such as the heating temperature and the use of flow through centrifugation. However, neither is applied in the same manner as the colostrum in the present invention to derive the fraction which is ultimately used to improve physical work capacity once ingested.

The Examiner then contends that the claims are identical to the cited disclosure of NZ282898 and therefore considered to be anticipated. However, the present claims recite "subjecting colostrum to ultrafiltration" whereas the citation refers to the colostrum being run through a column and the bound IGF-1 being eluted. Then it is not the colostrum that undergoes ultrafiltration it is the eluate that undergoes ultrafiltration. This is a distinguishing point. Accordingly, the composition referred to in the present claims and that of the citation

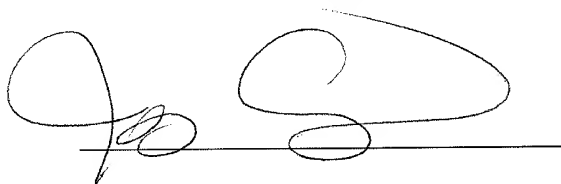
are different and therefore, a different composition is used for improving physical work capacity compared to that for providing a bone reinforcement effect which is useful for preventing and treating osteoporosis.

As anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 31 USPQ 1671 (Fed. Cir. 1994) and there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991), NZ282898 does not include all of the features of the claims and cannot anticipate the claims.

The claims currently under examination are novel in the light of NZ282898 and therefore, it is respectfully requested that the rejection be withdrawn.

It is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a large, stylized 'C'. The signature is written over a horizontal line.

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